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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/686,891

10/15/2003

Amir J. Tehrani

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LEVINE BAGADE HAN LLP  
2400 GENG ROAD, SUITE 120  
PALO ALTO, CA 94303

EXAMINER

ALTER, ALYSSA MARGO

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/686,891	<b>Applicant(s)</b> TEHRANI, AMIR J.	
	<b>Examiner</b> ALYSSA M. ALTER	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 123, 126, 141 and 149-160 is/are pending in the application.
- 4a) Of the above claim(s) 153-158 and 160 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 123, 126, 141, 149-152 and 159 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/15/10</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 15, 2010 has been entered.

### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 123, 126, 141, 149-152 and 159, drawn to a respiratory stimulation device to regulate inspiration, classified in class 607, subclass 42.
  - II. Claims 153-158 and 160, drawn to a respiratory device that manages pulmonary stretch receptors to maintain airway patency, classified in class 607, subclass 42. The inventions are distinct, each from the other because of the following reasons:

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation and effects. Invention I is used to

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regulates the breathing cycle, particularly inspiration. Invention II uses a threshold level measurement of a respiratory parameter to deliver stimulation to the patient in order to control or manage pulmonary stretch receptors to maintain airway patency. Invention II can be used for obstructive sleep apnea, while Invention I could be used to treat hyperventilation. These two inventions have different modes (the use of a threshold measure) and different effects (managing inspiration versus the pulmonary stretch receptors).

4. During a telephone conversation with Johnney Han on January 24, 2011 a provisional election was made without traverse to prosecute the invention I, claims 123, 126, 141, 149-152 and 159. Affirmation of this election must be made by applicant in replying to this Office action. Claims 153-158 and 160 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 123 and 126 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: sensing means that senses respiration activity to send to the stimulator. The claim does not indicate which element is responsible for the sensing of respiration activity.

***Claim Objections***

7. Claim 159 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claim 123, 126, 141 and 151-152 are rejected under 35 U.S.C. 102(e) as being anticipated by Ignagni et al. (US Patent Publication 20050021102 A1). Ignagni et al. discloses a device for managing respiration and conditioning the diaphragm of a patient. The system includes at least one electrode implanted into, or adjacent to, the phrenic nerve points in the diaphragm (page 2, paragraph 24).

10. As depicted in figure 4, the electrodes 120 are in communication with the electrical signal generator 110 in order to provide stimulation to condition the diaphragm. The electrical signal generator provides electrical stimulation to the at least one electrode to provide stimulation to the diaphragm and adjust the breathing cycle of the patient.

11. Additionally depicted in figure 4, “the system 400 can include a stimulation apparatus 430 that can include an electrical signal generator 110 (similar to the one described above) and a breathing sensor and control circuit 440 that is in electrical communication with the electrical signal generator 110 and the flow sensor 420. The breathing sensor and control circuit 440 can be configured to detect certain breathing attributes of the patient (e.g., the inspiration phase of a breath, the duration of the inspiration phase, the exhalation phase of a breath, the duration of the exhalation phase, tidal volume, and/or flow rate), convert these attributes to signals, and communicate these signals to the electrical signal generator 110” (pages 3-4, paragraph 36). Thus, the signal generator receives sensed respiration activity and generates electrical stimulation in response to the sensed respiration.

12. The electrical signal generator 110 can be configured to generate pulses” (page 2, paragraph 19). Since the electric stimulation is configured to deliver multiple pulses (i.e. more than one pulse), the stimulator is configured to delivers an electrical stimulation signal that comprising a “series” of pulses.

13. Additionally, the “electrical stimulation of the diaphragm can be synchronized with attempts at breathing or breathing made by the patient (e.g., on the patient's own or by the mechanical ventilator)” (page 4, paragraph 38). Furthermore, Ignagni et al. depicts the delivery of stimulation to enhance the contraction of the diaphragm (figure 5 and page 4, paragraph 42). Since the inhalation occurs when the diaphragm is contracting, the system provides stimulation during inhalation to enhance inspiration. Thus, the

stimulator delivers stimulation to cause the diaphragm to contract and thus is configured to deliver stimulation during inspiration.

14. As to claims 123 and 126, the electrical stimulation therapy is administered to patients that have inadequate inspiration duration and volumes due low diaphragm strength (page 4, paragraph 40). Therefore, the application of stimulation increases the inspiration volumes and duration as the diaphragm strengthens (page 4, paragraph 40).

15. As to claim 141, since the stimulation is provided to patients with inadequate respiration, the system necessarily elicits an inspiration rate different from the intrinsic inspiration, to provide the patient with more respiratory regularity and to strengthen the diaphragm.

16. As to claim 151, since the electrical stimulation system can stimulate the patient “continuously” with stimulation pulses (page 2, paragraph 17 and page 3, paragraph 30) the examiner considers the stimulation to be “sequential stimulation”. In addition, pulses with a 20mA amplitude and a 100 $\mu$ s duration are applied to the patient (page 3, paragraph 32). The examiner considers these pulses to be “low level” stimulation.

Therefore, Ignagni et al. discloses low level sequential stimulation applied to the patient.

17. As to claim 152, “Progressive inspiratory muscle weakness in ALS inevitably leads to carbon dioxide retention” (page 1, paragraph 5). Therefore, since the stimulator of Ignagni et al. conditions and strengthens the diaphragm, the stimulator is configured to deliver stimulation that manipulates the blood gases (i.e. the elimination of carbon dioxide) to treat the disordered breathing by the patient.

18. As to claim 159, the breathing sensor (pages 3-4, paragraph 36) is used to sense “respiration activity”. As such, the “sensed respiration activity” is the “sensed respiration activity”.

***Claim Rejections - 35 USC § 102/103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 149-150 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ignagni et al. (US Patent Publication 20050021102 A1). Ignagni et al. discloses a stimulator provides programmed stimulation (page 2, paragraph 19) to the patient through the at least one electrode and is thus “programmed to deliver a stimulation signal”. Therefore, the stimulation system of Ignagni et al. is necessarily programmed to deliver a stimulation signal to the at least one electrode, and as such is able to be programmed to deliver a signal to elicit either a slow elongated inspiration or a fast, short inspiration.

21. In the alternative, although the examiner considers Ignagni et al. to disclose the programming of the stimulator to deliver a signal to elicit either a slow elongated inspiration or a fast, short inspiration, it is not explicitly disclosed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation to elicit either a slow elongated inspiration or a fast, short inspiration in order to provide the predictable results of modifying the treatment to meet



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specific patient needs and requirements. Furthermore, such a modification can further synchronize or mimic the stimulation system with the patient's own respiratory attempts.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALYSSA M. ALTER whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alyssa M Alter/  
Examiner  
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